

EPA Registration Number 73049-460 Vol 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

May 1, 2013

I, Linda Hollis, Biochemical Pesticides Branch, Biopesticides & Pollution Prevention Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product(s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Lebanon) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Valent Biosciences Corporation
870 Technology Way
Libertyville, IL 600486316

EPA Registration Number: 73049-460
Name of Product: S-ABSCISIC ACID, TECHNICAL GRADE ACTIVE INGREDIENT

Linda Hollis
Risk Manager 91
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division
(7511P)





April 29, 2013

Linda Hollis
Biopesticides & Pollution Prevention Division
Document Processing Desk (CERT)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
703-308-8733

RE: Gold Seal Certificate Request for S-Abscisic Acid Technical Grade Active Ingredient (EPA Reg. No. 73049-460)

Dear Ms. Hollis:

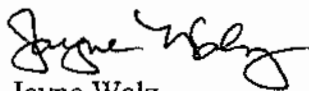
Valent BioSciences Corporation (VBC) is submitting the present request for five (5) copies of Gold Seal Certificate for **S-Abscisic Acid Technical Grade Active Ingredient** (EPA Reg. No. 73049-460) in Lebanon. The Gold Seal Certificates will be used to support five separate product registrations in Lebanon.

Present submission consists of:

- Application for Registration (EPA form 8570-1)
- Copy of payment confirmation made to Pay.gov in the amount of \$250
- Copy of the latest EPA stamped approved label.

Please contact me if you have any questions at 847-968-4771 or by e-mail at jayne.walz@valentbiosciences.com

Sincerely,


Jayne Walz
Regulatory Manager



Receipt for Section 3

S: 934864

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 73049 VALENT BIOSCIENCES CORPORATION

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 73049-460 Product Name: S-ABSCISIC ACID, TECHNICAL GRADE ACTIVE

Override#:

Me Too

Me Too

Section 3:

Product Name:

Application Date: 29-Apr-2013



OPP Rec'd Date: 30-Apr-2013



Front End Date: 30-Apr-2013



Risk Manager Send Date: 30-Apr-2013



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Other	Gold Seal Certificate

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Gold Seal Certificate

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

View/Edit



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-460	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) S-Absciscic Acid Technical Grade Active Ingredient	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation B70 Technology Way Libertyville, IL 60048 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

This is a request for five (5) Gold Seal Certificates for S-Absciscic Acid Technical Grade Active Ingredient for use in the registration process in Lebanon. All five of the GS will go to support individual end-use product registrations in Lebanon.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Not Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jayne Walz	Title Regulatory Manager	Telephone No. (Include Area Code) 847-958-4771
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager	
4. Typed Name Jayne Walz	5. Date April 29, 2013	

Commercial/financial information may be entitled to confidential treatment

Walz, Jayne

From: paygovadmin@mail.doc.twai.gov
Sent: Monday, April 29, 2013 9:29 AM
To: Walz, Jayne
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you chose the option to receive payment reminders in your user profile and this is a deferred or recurring payment, you will receive a reminder email several days before the payment is processed. You may change your payment reminder preferences and email address in your user profile at any time.

If you wish to cancel this recurring payment series, log in to your account at <https://www.pay.gov/> and click on the "Pending Payments List" option or contact Pay.gov Customer Service at (800) 624-1373.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25AHMT70
Agency Tracking ID: 74442306785
Account Holder Name: Valent BioSciences Corporation Transaction Type: ACH Debit Transaction Amount: \$250.00 Payment Date:
Apr 30, 2013 Account Type: Business Checking Routing Number: [REDACTED]

Transaction Date: Apr 29, 2013 10:29:14 AM Total Payments Scheduled: 1
Frequency: OneTime

Decision Number:
Registration Number:
Company Name: Valent BioSciences Corpor
Company Number: 73049
Action Code:

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

[illegible]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 30, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-478135
EPA File Symbol or Registration Number: 73049-460
Product Name: S-ABSCISIC ACID, TECHNICAL GRADE ACTIVE INGREDIENT
EPA Receipt Date: 30-Apr-2013
EPA Company Number: 73049
Company Name: VALENT BIOSCIENCES CORPORATION

JAYNE WALZ
VALENT BIOSCIENCES CORPORATION
870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048-6316

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

A handwritten signature in black ink, appearing to be "mjk", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Thomas Bade, Ph.D.
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

JUN 20 2012

Subject: Valent BioSciences Corporation; S-Absciscic Acid, Technical Grade Active Ingredient,
EPA Registration No. 73049-460
Application with Data to Amend the Manufacturing Process, Label and CSF; B680
D# 462249, Application Dated 3/30/12, PRIA Date 7/30/12

Dear Dr. Bade:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Chris Pfeifer at 703-308-0031 or by email at: pfeifer.chris@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,



Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

CONCURRENCES

SYMBOL	7511P							
SURNAME	PFEIFER							
DATE	6/20/12							

S-Abscisic Acid, Technical Grade Active Ingredient (S-ABA, VBC-30054)

FOR FORMULATION INTO PLANT GROWTH REGULATOR (PGR) PRODUCTS

FOR MANUFACTURING OR FORMULATION USE ONLY

Active Ingredient	
S-Abscisic Acid	97.9% w/w
Other Ingredients.....	2.1% w/w
Total.....	100.0% w/w

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call toll-free 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-847-968-4700.	

EPA Registration No. 73049-460
EPA Establishment No. 81887-CHN-002

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-847-968-4700

Net Content: 25 kg, 50 kg

ACCEPTED
JUN 202012

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 73049-460

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Mixers, loaders and handlers must wear the appropriate personal protective equipment (PPE): long sleeved shirt and pants, shoes and sock, and protective eyewear. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash-waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

S-Abscisic Acid is intended for use in the formulation of Plant Growth Regulator (PGR) products, to be applied to field and container-grown plants to induce and regulate PGR responses.

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator has complied with U.S. EPA data submission requirements regarding the support of such uses. Products made from this technical material will require registration with the U.S. Environmental Protection Agency (EPA).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container tightly closed when not in use. Store product in a cool and dry place. Avoid extended storage conditions at temperatures above 25°C (77°F).

Pesticide Disposal: To avoid wastes, use all material in this container according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry). Do not contaminate water when disposing of equipment wash-water or rinsate. Improper disposal of unused pesticide, wash-water or rinsate is a violation of federal law.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Completely empty drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Fill ¼ full with water. Shake for 10 seconds. Pour rinsate into manufacturing equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Completely empty drum contents into manufacturing equipment or a mix tank by shaking and tapping sides and bottom to loosen clinging particles. Fill container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Warranty and Disclaimer Statement:

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

Valent BioSciences Corp. ©2012

Label Review

File Symbol: 73049-460

Date: 6/13/12

Reviewer: Chris Pfeifer

Site/Use	[Res <input checked="" type="checkbox"/> /Ag <input type="checkbox"/> /Both] [Food /Non-Food <input checked="" type="checkbox"/> /Both]				
Tox Categories: (W)aived	[AcOral: 4 /AcDerm: 4 /AcInhl: 4 /EyeIrr: 3 /SkinIrr: 4 DermSens: N]				
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Restricted Use Pesticide	-----	-----	----		Ch 6
Product Name	✓				Pg 12-3
Compny Name and Info	✓				Pg 15-1
Identification Numbers	✓				Ch 14
Net Contents	✓				Ch 17
Ingredients Statement	✓			Percentage changed.	Ch 5
Label Claims	✓				Ch 12
Alternate Formula			✓		5-12
Precautionary Statements					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
KOROC	✓				3-1 & 9 7-3 & 4
Signal Word	✓				Ch 3 Ch 7 Ch 10
General Heading Precautionary Statements	✓				Ch 7
First Aid (PRN 20001-1)	✓				Ch 3 & 7
Hazards to Humans and Domestic Animals	✓				Ch 3, 7-3
PPE (WPS) Engineering Controls	✓				Ch 7,Pg 7-12 Pgs 10-4, 15
User Safety Requirements	✓				Ch 10
User Safety Recommendations	✓				Ch 10
Environmental Hazards	✓				Ch 8
Physical and Chemical Hazards			✓		Pg 3-4 Ch 9

Directions for USE (FIFRA Text, WPS plus Storage and Disposal)					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Header Directions for Use	✓				10-16
Violation of Federal Law text	✓				10-26, 11-7
WPS Text (PPE)	✓				Ch 10, 7-1 7-11
Non-WPS Text	✓				7-12, Ch 10
Storage and Disposal	✓				11-16, Ch 13

Directions for Use (General Instructions and Information)					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Instructions and Sub-Header	✓				
Chemigation / Prohibition	✓				PRN
REI	✓				Pg 10-20

Directions for Use (General Instructions and Information)					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Info. (non-site specific info. on uses, pests, mixing, and loading, tank mixing, etc.)	✓				
General Precautions and Restrictions	✓				
Directions for Use					
Directions for Application	✓				
Warranty Information					
Consistency with label instructions	✓				12-6
Not false or misleading	✓				
<p>"The warranty section contains an overly broad statement concerning limitations of liability. As such, this statement may be misleading and may constitute misbranding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is suggested that the existing statement be preceded by the phrase, "to the extent allowable by state law, or otherwise qualified to make it clear that this warranty is not intended to be a statement of law which implies that the buyer has no legal rights to recover damages from the manufacturer if he/she suffered a loss or injury from the product and concludes that it would be futile to pursue what might in reality be a valid claim."</p>					

BPPD Label Amendment Checklist

Fast Track ☐ and PRIA Actions B680 ☒ B73 ☐ & B90 ☐

EPA Reg. No.: 73049-460

RAL: Chris Pfeifer

Application Date: 3/30/12

#	Check list Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete, including package type? If NO, stop! Call applicant and have them correct application and resubmit.	√	
2.	Final printed labeling received for previous action? If NO, stop! E-mail applicant and request final printed labeling (FPL).	√	
3.	Data and Data Matrix present? (EPA Form 8570-35) A Data Matrix is not required for 100% repacks that have the same label uses as the parent product, and that derive their data from the formulator; nor is it required for minor amendments, which do not rely on data. In these cases, skip to Item 5.		√
a.	Using Selective Method (including the cite-all option under the Selective Method)? If using Cite-all method only, skip to Item 4.	√	
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.	√	
c.	Adequate product specific data?	√	
d.	Registered source used for active ingredient? If YES, skip to Item 5. If NO or if use not supported by registered source, generic data is necessary.	√	
e.	Data passed PR Notice 86-5 for formatting and MRID assignment?	√	
f.	Public copy of Data Matrix provided? (PRN 98-5)	√	
4.	Certification with Respect to Citation of Data present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5. (If no data are required, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.) NA <input type="checkbox"/>	√	
a.	Did applicant check a Method of Support?	√	
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	√	
c.	Is the form signed and dated?	√	
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources? If YES, is the required authorization letter included in application? NA <input type="checkbox"/>		√
5.	Label(s) Review Date of Label Review: 6/13/12		
a.	Label(s) in conformance with current <i>Label Review Manual</i> and appropriate REDS.	√	
b.	Labeling from Acute Toxicity, Product Chemistry, and Efficacy data for public health pests claimed on label.	√	
c.	Nominal concentration of active ingredient shown in ingredients statement.	√	
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram). NA <input checked="" type="checkbox"/>		
e.	Storage and disposal instructions agree with container types listed on application form.	√	
f.	Unique Product Name for Same Company (Check OPPIN).	√	
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES, RAL must evaluate label for compliance with 40 CFR 180.1071.		√
h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?		√
i.	If YES, National Organic Program or OMRI claims approved by Chris Pfeifer? NA <input checked="" type="checkbox"/> Labeling is acceptable. Corrections or changes are NOT necessary.	√	
j.	Comments: The only change to the label from the last label review (2/10) was a change in the percentage active ingredient.		

BASIC CHECK LIST FOR CONFIDENTIAL STATEMENT OF FORMULAS (CSF)

Please note that if you have any questions at any point, especially with chemical or microbial names, consult with a chemist/ product characterization scientist. It may be helpful to make a copy of the CSF for marking comments, questions, and needed corrections. Upon completion of this form, consult the above scientists. And have them check over the CSF along with your comments.

EPA Reg#/ File Symbol: 73049-460 CSF(s) dated: 3/8/12 REVIEW DUE DATE: 6/12/12

1. Compare CSF with prior CSF(s), and determine what is different.

Notes: Manufacturing Process changes altered impurity percentages.

2. Examine label. Does this product have food or feed use sites? It's an MP. Yes, for the EPs.

3. Is each field filled out on CSF? ☒yes ☐no

Missing: NA

4. Is box 18 signed? ☒yes ☐no

5. Are addresses complete, including zipcodes in boxes 1, 2, and 11? ☒yes ☐no

Deficiencies:

6. Have they enclosed a Material Safety Data Sheet (MSDS) for each new ingredient?

☒yes ☐no

Deficiencies: NA.

7. In column 10. for each component is the chemical name, trade name and CAS No. listed? Is it clear what each component is? For any microbial ingredient, in column 10 - the description should include Colony forming units per gram (CFU/g) and cell collection identity number (E.g. ATCC 889-34.) ☒yes ☐no

Deficiencies: NA. Everything is accounted for.

8. Using a chemical catalog, or Refs verify the CAS #, and chemical name for each component under consideration. Also Note any toxicological information disclosed in catalog.

Deficiencies: NA. CAS#s are correct.

9. Determine PC codes for each component and write these in "EPA USE ONLY" column. Does each component have a PC Code? If code(s) are not found, it may be necessary to send request form to RD. ☒yes ☐no

10. For each inert component determine whether it is listed under 40 CFR 180.100I (910-960). And write these codes in "EPA USE ONLY" column. (Names may be confusing- consult with a chemist if needed) *If this product is for feed or food use, all inert ingredients **MUST** have appropriate clearance.*

Deficiencies: No inerts. Impurities all clear.

11. For each inert component that does not have 40 CFR clearance determine whether it is a list 1, 2, 3, 4(a) , or 4(b) inert. Write this information in "EPA USE ONLY" column. References to consult: www.epa.gov/opprd001/inerts and FR Vol. 63, No. 121 pages 34384-34390. If any of the inert ingredients are listed as "No longer used" in the above FR vol.63 notice, or are on list 1 or 2, this is a problem to bring attention to chemist.

Problem inerts? NA. Impurities Clear.

12. If product used on food or feed, confirm active ingredient(s) has an established tolerance or exemption from food tolerance. (Consult Alphabetical listing in part 180 of 40 CFR pages 296-300, or the pesticide petition file jacket) ☐ yes ☒ no

Deficiencies: 180.1281.

13. Do certified limits for EACH component agree with 40 CFR 158.175?

Amount in Column 13 b.	Prescribed limits	Upper Limit	Lower Limit
≤1%	$N \pm 10\%N$	$N \times 1.1$	$N \times 0.9$
>1% but ≤20%	$N \pm 5\%N$	$N \times 1.05$	$N \times 0.95$
>20%	$N \pm 3\%N$	$N \times 1.03$	$N \times 0.97$

N= amount in Column 13 b. = nominal concentration

Calculate upper and lower limits using table above and compare with those listed in columns 14 a. and 14 b. of submitted CSF. If they do not agree, identify difference(s): Proposed limits of nominal active accepted.

14. Does the sum of the numbers in column 13. a. equal total listed in box 17?

☒ yes ☐ no

15 Does column 13. b. add up to 100%? ☒ yes ☐ no

16. If Alternative Formulation box is checked in box A- Is there another CSF for a Basic Formulation on file?? ☐ yes ☐ no ☒ NA

17. Other issues? No.

S-Absciscic Acid
PC Code: 272000
Type of Review: Product Chemistry

DP Number: 462249
EPA Reg. No.: 73049-460



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE: 06/12/2012

SUBJECT: Science Review in Support of the Registration of S-Absciscic Acid Technical Grade Active Ingredient, Containing 97.9% S-Absciscic Acid (ABA) as its Active Ingredient. Review of Product Chemistry Data: New 5-Batch Analysis and Certified Limits.

Decision Number: 462249
DP Number: 400801
EPA File Symbol Number: 73049-460
Chemical Class: Biochemical
PC Code: 272000
CAS Number: 21293-29-8
Tolerance Exemptions: None
MRID Numbers: 487654-01 & -02.

FROM: Russell S. Jones, Ph.D., Senior Scientist /s/ 06/12/2012
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Chris Pfeifer, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

The registrant, Valent Biosciences Corporation (Valent), requests the addition of a new manufacturing site, using the same manufacturing process. In support of the amendment, the registrant has submitted a 5-batch analysis and certified limits.

S-Abscisic Acid
PC Code: 272000
Type of Review: Product Chemistry


DP Number: 462249
EPA Reg. No.: 73049-460

RECOMMENDATIONS AND CONCLUSIONS

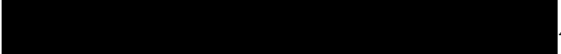
The data submitted for the Preliminary Analysis and Certification of Limits for S-Abscisic Acid Technical Grade Active Ingredient, containing 97.9% S-Abscisic Acid (ABA) as its active ingredient are **ACCEPTABLE**. No additional data are required to support the change in manufacturing source.

STUDY SUMMARIES

Preliminary Analysis (OCSPP 830.1700; MRID 48765401): Six individual batches of S-ABA Technical were analyzed by reversed-phase HPLC with UV detection at 262 nm (for details of method, see MRID 48765401, Confidential Appendix, Attachment 1). The method was used to quantify the amount of S-ABA in each batch and the impurities. Selected lots of the S-ABA technical were also analyzed using additional non-HPLC Methods. The percentage of S-ABA and impurities in 6 lots of S-ABA technical, as analyzed by HPLC, are provided in Table 1.



Additional analyses conducted by Gabraith Laboratories (see MRID 48765401, Confidential Appendix Table 2 & 3, p. 12 & 13, respectively; and Confidential Appendix, Attachments 2 and 3) were provided showing other very minor impurities, individually <0.1% of the product by weight.

The mean percentage of S-ABA was determined to be 97.871% (range: 97.633-98.136%) with  All impurities were reported to the Agency for previously submitted and reviewed analyses, although at slightly different mean percentages.

Sample chromatograms were provided for all analyses.

Classification: **ACCEPTABLE**, no additional data are required.

S-Absciscic Acid
PC Code: 272000
Type of Review: Product Chemistry

DP Number: 462249
EPA Reg. No.: 73049-460

Cortication of Limits (OCSP 830.1750; MRID 48765402): Certified limits proposed by the registrant are reflected in the data provided by the registrant in the preliminary analysis described above and in MRID 48765401. The current certified limits originally proposed for S-ABA technical are not being changed. The most recent 6 batch analysis demonstrates that the current values are within the originally proposed certified limits. Comparisons of the analyses conducted in 2011 and 2012 are provided in MRID 48765402 (Confidential Appendix, Table 4, p. 7); proposed certified limits are provided in MRID 48765402 (Confidential Appendix, Table 4, p. 8)

Classification: ACCEPTABLE, no additional data are required.

NO DERs WERE WRITTEN FOR THIS MEMORANDUM

cc: R. S. Jones, C. Pfeifer, BPPD Chron File, IHAD/ARS
R. S. Jones, Ph.D., Sr. Scientist, FT, PY-S: 06/12/2012

BPB BPPD New Product/Non-Registered AI Source Readiness Screen

~~*****Contains Confidential Business Information*****~~

Date: 3/29/2012

Review Date: 3/29/2012

File Symbol No.: 73049-460

Reviewers: Gina Burnett

Comments: This is a PRIA Amendment to add a new manufacturing site but using the same manufacturing process. The applicant has submitted a 5-batch analysis manufactured at the new site and certified limits for the new site. The product is a manufacturing-use product with unregistered source of active ingredient plus impurities, no inerts. The product is used for seed production for non-food uses.

The applicant states in his memo dated March 8, 2012 that this change in manufacturing site also applies to EPA Reg Nos:

73049-461

73049-462

73049-474

Andy – please make sure these actions are tracked/assigned. The new CSFs for these Reg Nos are included in this package.

Pass/Fail: PA55

Hours Worked: 1.0

	Checklist Item	Yes	No	N/A	Comments
1.	Forms				
a.	8570-1: Application for Registration	X			
b.	8570-4: CSF	X			
c.	8570-27: Formulator's Exemption			X	
d.	8570-34: Certification with Respect to Data	X			
e.	8570-35: Data Matrix	X			
2.	Confidential Statement of Formula (CSF)-review for alternate formulations too				
a.	Signed and dated	X			
b.	Food-use? (If no, skip to 1e.)		X		
c.	All inerts cleared for food-use			X	
d.	Active cleared for food-use			X	

e.	All inerts cleared for nonfood-use (skip if food-use)	X			
f.	Conventional or antimicrobial actives present?		X		
g.	CSF accurately reflects label	X			
h.	Active(s) + Inert(s) = 100%	X			
i.	CAS #s for all inerts			X	
j.	Chemical names provided for inerts			X	
k.	Units in all applicable boxes	X			
l.	Proprietary inerts? If so, is info. on file with the Agency?		X		
m.	Supplier information adequately listed	X			
n.	Certified limits correct?	X			
o.	If certified limits are outside recommended range, explanation provided?			X	
p.	Microbial: culture collection reference			X	
q.	Microbial: strain designation for a.i.			X	
r.	Microbial: potency provided with a.i.			X	
s.	Alternate formulations?		X		
t.	Are alternate formulations actually alternate and not a new product?			X	
3.	Data Matrix-ACTIVE INGREDIENT/MP				
a.	Separate data matrix for the source of AI		X		
b.	All product chemistry data requirements addressed (guideline by guideline)	X			
c.	All toxicology data requirements addressed (guideline by guideline)	X			
d.	All nontarget toxicology data requirements addressed (guideline by guideline)	X			
e.	Reflects info. reported on CSF (e.g.: identity of AI)	X			
Note for 3b.-d. above: If not addressed in data matrix, may be addressed in elsewhere in submission					
5.	Data Requirements-Guideline Studies				
Note: This section is for submitted guideline studies only. See below for waivers and rationales.					

a.	Product chemistry: do all submitted studies appear to satisfy the data requirements?	X			
b.	Toxicology: do all submitted studies appear to satisfy the data requirements?			X	
c.	Nontargets: do all the submitted studies appear to satisfy the data requirements?			X	
d.	Other (residue data, special studies, etc.)		X		
6.	Data Requirements- Waivers				
Note: This section is for waivers only. This does not apply to rationale submitted to satisfy the data requirements.					
a.	Are there any requests for waivers? Please note.		X		
b.	For each applicable data requirement, does the waiver request have a separate scientific rationale justifying why testing is not applicable?			X	
c.	Does each waiver request seem reasonable and justified?			X	
7.	Data Requirements- Rationales/Literature				
Note: This section is for rationales only. This does not apply to requests submitted to waive the data requirements.					
a.	Have rationales been submitted in lieu of guideline studies? Please note.		X		
b..	Does each rationale have scientific literature citations where applicable?			X	
c.	Are the rationale and scientific citations organized in reasonable order to facilitate timely review and is each guideline addressed individually?			X	
d.	Are copies of cited scientific literature included in the package?			X	
e.	Does the rationale appear to be reasonable and scientific?			X	

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3-9-12

Experts In-Processing Signature: MF Harrington Date 3-23-12 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>73049-460</u>		EPA Receipt Date: <u>3-9-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments: Studies passed 11-3 review. 487654.

CSF

- Technical - Technical & Impurities only, no inerts to review
End use Product (ProTone SG) - Inerts approved for Food Use under 40 CFR 180.970, Pre-Harvest
End use Product (Contego ProSL) - Inerts approved for Non-Food Use
End use Product (Massive BioNIM) - Inerts approved for Non-Food Use
3/19/12 - An e-mail was sent to the registrant regarding a deficiency on the Certification Form and inert issues
- An Inert clearance status form was sent.
- Received a corrected Certification Form and a revised CSF with corrections.

Jacket passes

TO 3/21/12

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period. otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opbpbpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Receipt for Section 3			
S:	913147	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Application Type:	Amendment	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Company:	73049 VALENT BIOSCIENCES CORPORATION		V
Risk Manager:	Biologicals & Pollution Prevention Division PM Team S1		
Product #:	73049-460	Product Name:	S-ABSCISIC ACID, TECHNICAL GRADE ACTIVE
Override#:			
Me Too Section3:		Me Too Product Name:	
Application Date:	08-Mar-2012	OPP Rec'd Date:	09-Mar-2012
Front End Date:	12-Mar-2012	Risk Manager Send Date:	
FFS Due Date:		Negotiated Due Date:	
OPP Target Date:			
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>
Receipt Description:		View/Edit	
Label amendment		New Ingredient Request Date:	
		New Ingredient Received Date:	
Form A:	<input type="checkbox"/>	Signature Date:	
Form B:	<input type="checkbox"/>	Signature Date:	

Decis# 462249

B680

FFS start 3/30/12

PRIA due 7/30/12

Phase 1 = 4/30/12

No P2 or P3

P4 - 6/14/12

P5 - 7/30/12



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Valent BioSciences, EPA # 73049-460	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Valent BioSciences / S-Abscisic Acid (VBC-30054)	PM#	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corp. 870 Technology Way Libertyville IL, 60048 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Register a new site for manufacture, same manufacturing process, same company, new facility. Updated five lot analysis with samples manufactured at the new site.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Thomas Bade Ph.D.		Title Regulatory Manager		Telephone No. (Include Area Code) 847-968-4726	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Manager			
4. Typed Name Thomas Bade		5. Date 3/8/12			



48765400

March 8, 2012

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. Chris Pfeifer
Regulatory Action Leader
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency

Subject: Valent BioSciences Corp.
Registration of a new facility for Manufacturing of S-Abscisic Acid,
(EPA Reg.No.73049-460)

The following submission is an analysis of five (5) typical lots for the biochemical plant growth regulator S-Abscisic Acid (S-ABA, VBC-30054), EPA Reg.No.73049-460. The manufacturer has completed construction of a new manufacturing facility (EPA Establishment # 81887-CHN-002) and has produced five typical lots. The manufacturing company has not changed, the manufacturing process has not changed, only the facility location in which the manufacturing occurs has changed.

Valent BioSciences has analyzed these five typical lots to insure that the new facility is producing S-Abscisic Acid at the same certified limits as currently registered.

All impurities are the same as currently certified, within the allowed limits currently certified and the mass balance is as currently presented. We are submitting this five-lot analysis and requesting the registration of this manufacturing site for the production of S-Abscisic acid.

Valent BioSciences believes this action fits the category of B680 "Label amendment requiring data submission" with a cost of \$4,631 and a PRIA timeline of 5 months.

Valent BioSciences has previously submitted payment for this registration action; [Pay.gov tracking ID: 255VVD58, Name of account: Valent BioSciences Corp., Payment amount: \$4,631.00, Payment date: March 8, 2012].



Included in this application are; -a transmittal document that lists two (2) new studies submitted in support of this submission, -three copies of each of these studies, -a new CSF for Reg # 73049-460 with the manufacturing location updated and the nominal and limits updated (one copy with the changes highlighted and one copy without highlighting), -a new CSF for Reg # 73049-461 ProTone SG with the manufacturing location updated and the nominal % for the active ingredient updated (one copy with the changes highlighted and one copy without highlighting), -a new CSF for Reg # 73049-462 ConTego Pro SL with the manufacturing location updated and the nominal % for the active ingredient updated (one copy with the changes highlighted and one copy without highlighting), and -a new CSF for Reg # 73049-474 Massivo BioNik with the manufacturing location updated and the nominal % for the active ingredient updated (one copy with the changes highlighted and one copy without highlighting).

This submission is organized as follows:

Cover letter

Administrative Documents

Transmittal Document (listing all studies submitted)

Form 8570-1 EPA Pesticide Registration Application form

Form 8570-34 Certification with Respect to Citation of Data

Copy of the Pay.gov tracking receipt, [Pay.gov tracking ID: 255VVD58]

Form 8570-35 Data Matrix (VBC-30054 [TGAI]),

Form 8570-4 CSF Reg # 73049-460 (VBC-30054 [TGAI])

Form 8570-4 CSF Reg # 73049-461 ProTone SG

Form 8570-4 CSF Reg # 73049-462 ConTego Pro SL

Form 8570-4 CSF Reg # 73049-474 Massivo BioNik

Label for S-Abscisic Acid (VBC-30054)

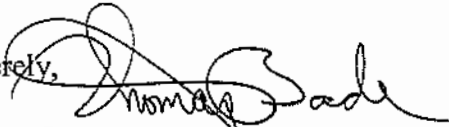
Three copies of each study submitted. The new reports included in this submission are;

Guideline	Data Requirement	VBC Report Number, issue date
830.1700	Preliminary Analysis	Report #: VBCL12-48060-01; S-ABA 312-01 (March 8, 2012)
830.1750	Certified Limits	Report #: S-ABA 30054; 312-02 (March 8, 2012)

The reports contained within this submission pertain to analysis of production lots of the S-Abscisic acid TGAI produced at the new facility and discussion of the certified limits.

If I can be of any assistance during the review of this application please contact me at (847)-968-4726 (or at thomas.bade@valentbiosciences.com).

Sincerely,


Thomas Bade Ph.D.
Regulatory Manager
Valent BioSciences

Transmittal Document

S-Absciscic Acid (S-ABA)
Technical grade Active Ingredient
EPA Registration # 73049-460

Company

Submitter: Valent BioSciences Corp.
870 Technology Way
Libertyville, IL 60048

Agent: Thomas Bade Ph.D.
Regulatory Manager, Regulatory Affairs
847-968-4726

Regulatory Action: In support of the registration of a new manufacturing facility for
Technical Grade Active Ingredient (TGAI) S-Absciscic Acid,
Reg # 73049-460.

Transmittal Date: March 8, 2012

Listing of Submitted Studies:

Document 1

Title: Analysis and Certification of Product Ingredients in Selected Lots of S-Absciscic
Acid

Data requirements: OPPTS 830.1700, 830.1750

Study Date: March 8, 2012

Performing Laboratory: Valent BioSciences Corp. Research Center.
6131 Oakwood Road
Long Grove, IL 60047

Project ID: VBCL12-48060-01; S-ABA 312-01

MRID No.: 48765401

Document 2

Title: S-Abscisic Acid: VBC-30054 TGAI Product Chemistry: Certification of Limits

Data requirements: OPPTS 830.1750

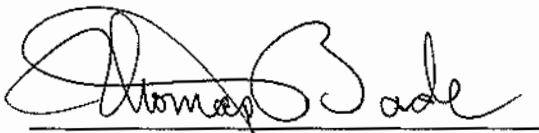
Study Date: March 8, 2012

Performing Laboratory: Valent BioSciences Corp.

870 Technology Way
Libertyville, IL 60048

Project ID: S-ABA 30054; 312-02

MRID No.: 48765402

Company Official: 
Signature

3/8/12
Date

Company Name: Valent BioSciences Corporation

Company Contact: Thomas Bade Ph.D.

847-968-4726
Phone



RE: Inert Issues and Application Deficiency (73049-460)
Bade, Thomas
to:
Tracy Jackson
03/19/2012 09:47 AM
Cc:
"Herrero, Maria"
Hide Details
From: "Bade, Thomas" <Thomas.Bade@valentbiosciences.com>

To: Tracy Jackson/DC/USEPA/US@EPA

Cc: "Herrero, Maria" <Maria.Herrero@valentbiosciences.com>

History: This message has been forwarded.

Tracy: Thank you for your direction. I will send another form (8570-34) with the correct box designated.

In the inert status form for ConTego Pro SL you listed [REDACTED] as having the wrong CAS number [REDACTED]. The [REDACTED] should be listed as [REDACTED] (also call [REDACTED]). This has the CAS Number [REDACTED]. I will edit the CSF and send a new copy. Do I send this to the front end screen and if so what designation should I include to make sure it gets to you, or directly to you?

~~For the Massivo BioNik Plant Growth Regulator, this is a seed treatment end use formulation used for Hybrid seed production. It is used on seed used to make hybrid seeds. It did not receive a tolerance or an exemption for a tolerance. It is a non food use. Does this alleviate the concerns regarding the non-food use status of [REDACTED]. The [REDACTED] name on the specification sheets for [REDACTED]~~

From: Tracy Jackson [mailto:Jackson.Tracy@epamail.epa.gov]
Sent: Monday, March 19, 2012 7:23 AM
To: Bade, Thomas
Subject: Inert Issues and Application Deficiency (73049-460)

Dear Mr. Bade,

I am contacting you regarding your submission of **S-Abscisic Acid, Technical Grade Active Ingredient (73049-460)**. There were some inert issues on the Confidential Statement of Formula of the end use products and a deficiency in the application packet.

Application Deficiency:

On the Certification with Respect to Citation of Data (form 8570-34), under Section I: Method of Data Support. The box on the right should be the checked which states "I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used)."

Please see inert status forms below for inert issues.

(See attached file: Inert Status.doc)(See attached file: Inert Status form.doc)

Please send all corrections to jackson.tracy@epa.gov

If you have any questions I can reached at 703-308-7227

Thank you

Tracy Jackson
Macfadden/EPA Contractor
2777 S. Crystal Drive
Arlington, VA 22202



RE: Inert Issues and Application Deficiency (73049-460)
Bade, Thomas
to:
Tracy Jackson
03/19/2012 10:26 AM
Hide Details
From: "Bade, Thomas" <Thomas.Bade@valentbiosciences.com>

To: Tracy Jackson/DC/USEPA/US@EPA

Inert ingredient information may be entitled to confidential treatment

History: This message has been replied to.

I will send the form and CSF by E-Mails. I have found an alternate name OptiXan Dispersible Transparent but not OptiXan Dispersible T.

From: Tracy Jackson [<mailto:Jackson.Tracy@epamail.epa.gov>]
Sent: Monday, March 19, 2012 9:13 AM
To: Bade, Thomas
Subject: Fw: Inert Issues and Application Deficiency (73049-460)

Hello Mr. Bade,

You can send the the revised CSF directly to me. Will you be sending it by e-mail? As for [REDACTED]
[REDACTED] an alternate name for it also?

Thank you

Tracy Jackson
Macfadden/EPA Contractor
2777 S. Crystal Drive
Arlington, VA 22202

----- Forwarded by Tracy Jackson/DC/USEPA/US on 03/19/2012 10:08 AM -----

From: "Bade, Thomas" <Thomas.Bade@valentbiosciences.com>
To: Tracy Jackson/DC/USEPA/US@EPA
Cc: "Herrero, Maria" <Maria.Herrero@valentbiosciences.com>
Date: 03/19/2012 09:47 AM
Subject: RE: Inert Issues and Application Deficiency (73049-460)

Inert ingredient information may be entitled to confidential treatment

Tracy: Thank you for your direction. I will send another form (8570-34) with the correct box designated.

In the inert status form for ConTego Pro SL you listed [REDACTED] as having the wrong CAS number [REDACTED]. The [REDACTED] should be listed as [REDACTED] (also call [REDACTED]). This has the CAS Number [REDACTED]. I will edit the CSF and send a new copy. Do I send this to the front end screen and if so what designation should I include to make sure it gets to you, or directly to you?

For the Massivo BioNik Plant Growth Regulator, this is a seed treatment end use formulation used for Hybrid seed production. It is used on seed used to make hybrid seeds. It did not receive a tolerance or an exemption for a tolerance, it is a non-food use. Does this alleviate the concerns regarding the non-food use status of [REDACTED]

From: Tracy Jackson [mailto:Jackson.Tracy@epamail.epa.gov]

Sent: Monday, March 19, 2012 7:23 AM

To: Bade, Thomas

Subject: Inert Issues and Application Deficiency (73049-460)

Dear Mr. Bade,

I am contacting you regarding your submission of **S-Abscisic Acid, Technical Grade Active Ingredient (73049-460)**. There were some inert issues on the Confidential Statement of Formula of the end use products and a deficiency in the application packet.

Application Deficiency:

On the Certification with Respect to Citation of Data (form 8570-34), under Section I: Method of Data Support. The box on the right should be the checked which states "I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used)."

Please see inert status forms below for Inert issues.

(See attached file: Inert Status.doc)(See attached file: Inert Status form.doc)

Please send all corrections to jackson.tracy@epa.gov

If you have any questions I can reached at 703-308-7227

Thank you

Tracy Jackson
Macfadden/EPA Contractor
2777 S. Crystal Drive
Arlington, VA 22202



Inert Issues and Application Deficiency (73049-460)
Tracy Jackson to: thomas.bade

03/19/2012 08:23 AM

Dear Mr. Bade,

I am contacting you regarding your submission of S-Abscisic Acid , Technical Grade Active Ingredient (73049-460). There were some inert issues on the Confidential Statement of Formula of the end use products and a deficiency in the application packet.

Application Deficiency :

On the Certification with Respect to Citation of Data (form 8570-34), under Section I: Method of Data Support. The box on the right should be the checked which states "I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used)."

Please see inert status forms below for inert issues .



Inert Status.doc Inert Status form.doc

Please send all corrections to jackson.tracy@epa.gov

If you have any questions I can reached at 703-308-7227

Thank you

Tracy Jackson
Macfadden/EPA Contractor
2777 S. Crystal Drive
Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 13, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-462249
EPA File Symbol or Registration Number: 73049-460
Product Name: S-ABSCISIC ACID, TECHNICAL GRADE ACTIVE INGREDIENT
EPA Receipt Date: 09-Mar-2012
EPA Company Number: 73049
Company Name: VALENT BIOSCIENCES CORPORATION

THOMAS BADE
VALENT BIOSCIENCES CORPORATION
870 TECHNOLOGY WAY, SUITE 100
LIBERTYVILLE, IL 60048-6316

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B680

AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8715.

Sincerely,

A handwritten signature in black ink, appearing to read "Jes" or similar, written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

J
{913147*~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr. 91

Receipt No.

S-

913147

EPA File Symbol/Reg. No.

73049-460

Pin-Punch Date:

3/9/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B680

Granted: B680

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐

Uncleared Inert in Product

Reviewer: Andrew Bryce Land

Date: 3/12/12

Remarks:

Receipt for Section 3

S: 813147

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 73049 VALENT BIOSCIENCES CORPORATION

V

Risk Manager: Biologicals & Pollution Prevention Division; PM Team 91

Product #: 73049-460 Product Name: S-ABSCISIC ACID, TECHNICAL GRADE ACTV

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 08-Mar-2012

iel

OPP Rec'vd Date: 09-Mar-2012

iel

Front End Date: 12-Mar-2012

iel

Risk Manager Send Date:

iel

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Dec
Study	
Paper Label	
<	>

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

View/Edit

Commercial/financial information may be entitled to confidential treatment

Bade, Thomas

From: paygovadmin@mail.doc.twai.gov
Sent: Wednesday, March 07, 2012 11:14 AM
To: Bade, Thomas
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you chose the option to receive payment reminders in your user profile and this is a deferred or recurring payment, you will receive a reminder email several days before the payment is processed. You may change your payment reminder preferences and email address in your user profile at any time.

If you wish to cancel this recurring payment series, log in to your account at <https://www.pay.gov/> and click on the "Pending Payments List" option or contact Pay.gov Customer Service at (800) 624-1373.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 255VVD58
Agency Tracking ID: 74289493162
Account Holder Name: Valent BioSciences Corporation Transaction Type: ACH Debit
Transaction Amount: \$4,631.00 Payment Date: Mar 8, 2012 Account Type: Business Checking
Routing Number: [REDACTED] Account Number: [REDACTED]

Transaction Date: Mar 7, 2012 12:14:28 PM Total Payments Scheduled: 1
Frequency: OneTime

Decision Number:
Registration Number:
Company Name: Valent BioSciences Corpor
Company Number: 73049
Action Code:

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Valent BioSciences, 870 Technology Way, Libertyville Illinois 60048	EPA Registration Number/File Symbol 73049-460
Active Ingredient(s) and/or representative test compound(s) S- Absciscic acid (EPA Registration # 73049-460)	Date October 25, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Plant growth regulator - Technical Grade Active Ingredient	Product Name S-Absciscic acid (S-ABA)

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and I have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 3/19/12	Typed or Printed Name and Title Thomas Bade, Regulatory Manager
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 13, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VALENT BIOSCIENCES CORPORATION
870 TECHNOLOGY WAY, SUITE 100
LIBERTYVILLE, IL 60048-6316

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 09-MAR-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

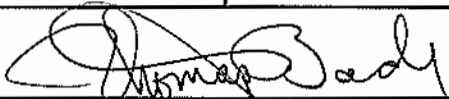


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 3/8/2012		EPA Reg No./File Symbol 73049-460		Page 1 of 5	
Applicant's/Registrant's Name & Address Valent BioSciences Corporation, 870 Technology Way, Livertyville, IL, 60048		Product S-Absciscic Acid (VBC-30054); TGA1 for Manufacturing Use Only			
Ingredient S-Absciscic Acid (S-ABA); (S)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-2-cyclohexen-1-yl)-3-methyl-[2Z,4E]-pentadienoic acid, [CAS # 21293-29-8]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
880.1100, 880.1200, 880.1400	Integrated Manufacturing Process S-ABA # 30054; 056-4	46895601	Valent BioSciences EPA # 73049	OWN	
880.1100, 880.1200, 880.1400	Integrated Manufacturing Process S-ABA # 30054; 027-1	47067903	Valent BioSciences EPA # 73049	OWN	
830.1700, 830.1750, 830.1800	Product Chemistry: Analysis, Cert limits, # 30054; 056-5	46895602	Valent BioSciences EPA # 73049	OWN	
830.1700, 830.1750, 830.1800	Product Chemistry: Analysis, Cert limits, # 30054; 027-2	47067904	Valent BioSciences EPA # 73049	OWN	
830.1700	Technical 5-Lot Analysis, PTRL # 1473W	47470401	Valent BioSciences EPA # 73049	OWN	
830.1700	VBC-30054 Product Chem: Cert Limits # 30054; 127-2	47470403	Valent BioSciences EPA # 73049	OWN	
830.1800	Anal Mtd; Validation TGA1 and formulation, PTRL# 1442W	46895610	Valent BioSciences EPA # 73049	OWN	
830.1700	Characterization of 1-4 diol # VBCL07-48060-01	47470520	Valent BioSciences EPA # 73049	OWN	
830.0000	30054 Phys Chem Summary, # 30054; 056-3	46895603	Valent BioSciences EPA # 73049	OWN	
830.6302, 830.6303, 830.6304	30054 Phys Chem Characteristics PTRL # 1438W	46895604	Valent BioSciences EPA # 73049	OWN	
830.6313	30054 Stability, Temp, Metals & Ions PTRL # 1618W-1	47470406	Valent BioSciences EPA # 73049	OWN	
830.6315	30054 Flammability, Explodability, HLS # ZAB0083/072858	47470410	Valent BioSciences EPA # 73049	OWN	
830.7000, 830.7300	30054 pH, PTRL # 1558W	46895607	Valent BioSciences EPA # 73049	OWN	
830.7200, 830.7300	30054 Melting Point, Density PTRL # 1438W	46895604	Valent BioSciences EPA # 73049	OWN	
830.7840, .7550, .7560, .7570	30054 water Sol, Part Coef, Diss Const, PTRL#1437W	46895605	Valent BioSciences EPA # 73049	OWN	
Signature 			Name and Title Thomas Bada, Regulatory Manager		Date 3/8/12

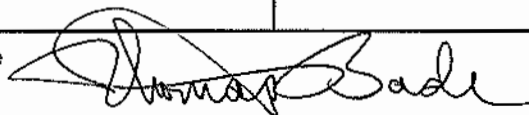


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DATA MATRIX

Date 3/8/2012		EPA Reg No./File Symbol 73049-460		Page 2 of 5	
Applicant's/Registrant's Name & Address Valent BioSciences Corporation, 870 Technology Way, Livertville, IL, 60048		Product S-Abscisic Acid (VBC-30054); TGA for Manufacturing Use Only			
Ingredient S-Abscisic Acid (S-ABA); [S]-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-2-cyclohexen-1-yl)-3-methyl-(2Z,4E)-pentadienoic acid, [CAS # 21293-29-8]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.0000	Lomon Phys Chem Summary # 2004B-04	47470413	Valent BioSciences EPA # 73049	OWN	
830.1800	Analytical HPLC Method # VBC-M04001.2		Valent BioSciences EPA # 73049	OWN	
830.7050	30054 - UV/Vis Abs, Spectra DeCode REP-RC-2004-048	47470414	Valent BioSciences EPA # 73049	OWN	
830.7050	30054 - Ref Std retest DeCode REP-RC-2005-039	47470415	Valent BioSciences EPA # 73049	OWN	
830.7950	30054 - Vapour Pressure, PTRL # 1436W-1	46895606	Valent BioSciences EPA # 73049	OWN	
830.7840	30054 - Solubility in Organic Solvents, PTRL # 1730W-1	47470411	Valent BioSciences EPA # 73049	OWN	
830.2110	30054 - Hydrolysis at pH 4, 7, 9, PTRL # 1729W-1	47470412	Valent BioSciences EPA # 73049	OWN	
830.6317, 830.6320	30054 -Storage Stability & Corrosion PTRL # 2048W	48674901	Valent BioSciences EPA # 73049	OWN	
Signature 			Name and Title Thomas Bade, Regulatory Manager		Date 3/8/12

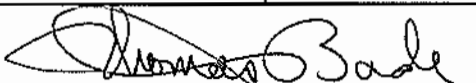


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WASHINGTON, D.C. 20460

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DATA MATRIX

Date 3/8/2012		EPA Reg No./File Symbol 73049-460		Page 3 of 5	
Applicant's/Registrant's Name & Address Valent BioSciences Corporation, 870 Technology Way, Livertyville, IL, 60048		Product S-Abscisic Acid (VBC-30054); TGA for Manufacturing Use Only			
Ingredient S-Abscisic Acid (S-ABA); (S)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-2-cyclohexen-1-yl)-3-methyl-(2Z,4E)-pentadienoic acid, (CAS # 21293-29-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	30054 - Acute Oral, PSL # 16974	46895611	Valent BioSciences EPA # 73049	OWN	
870.1200	30054 - Acute Dermal, PSL # 16975	46895612	Valent BioSciences EPA # 73049	OWN	
870.1300	30054 - Acute Inhalation, PSL # 17515	46895613	Valent BioSciences EPA # 73049	OWN	
870.2400	30054 - Primary Eye Irritation, PSL # 16976	46895614	Valent BioSciences EPA # 73049	OWN	
870.2500	30054 - Primary Dermal Irritation, PSL # 16977	46895615	Valent BioSciences EPA # 73049	OWN	
870.2600	30054 - Dermal Sensitization, PSL # 16978	46895616	Valent BioSciences EPA # 73049	OWN	
870.1300	30054 - Acute Inhalation, PSL # 27098		Valent BioSciences EPA # 73049	OWN	
Signature 			Name and Title Thomas Bade, Regulatory Manager		Date 3/8/12

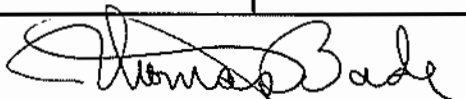


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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 3/8/2012			EPA Reg No./File Symbol 73049-460		Page 4 of 5
Applicant's/Registrant's Name & Address Valent BioSciences Corporation, 870 Technology Way, Livertville, IL, 60048			Product S-Absciscic Acid (VBC-30054); TGA for Manufacturing Use Only		
Ingredient S-Absciscic Acid (S-ABA); (S)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-2-cyclohexen-1-yl)-3-methyl-(2Z,4E)-pentadienoic acid, [CAS # 21293-29-8]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3100	90-Day Oral Toxicity, CRL # 28084	47470510	Valent BioSciences EPA # 73049	OWN	
870.3250	21-Day Repeat Dermal, CRL # 27971	47470508	Valent BioSciences EPA # 73049	OWN	
870.3700	Teratology, preliminary Prenatal Dev, CRL # 28566	47470511	Valent BioSciences EPA # 73049	OWN	
870.3700	Teratology, Prenatal Development, # WIL-505004	47470512	Valent BioSciences EPA # 73049	OWN	
870.5100	Bacterial Reverse Mutation, Covance # 7194-101	47030901	Valent BioSciences EPA # 73049	OWN	
870.5300	In vitro cell gene mutation, Covance # 7194-103	47005301	Valent BioSciences EPA # 73049	OWN	
870.5375	In vitro cell gene mutation, Covance # 7194-102	47005302	Valent BioSciences EPA # 73049	OWN	
870.3050	4-week Oral Toxicity, CRL # 27720	47470509	Valent BioSciences EPA # 73049	OWN	
870.3100	13-Week Oral Toxicity, CRL # 28084	47470510	Valent BioSciences EPA # 73049	OWN	
N/A	Endocrine Disruptor Testing, #VBC-SCC ABA 12-14-07	47470513	Valent BioSciences EPA # 73049	OWN	
Signature 			Name and Title Thomas Bade, Regulatory Manager		Date 3/8/12

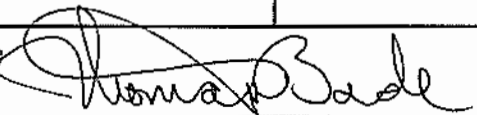


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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 3/8/2012			EPA Reg No./File Symbol 73049-460		Page 5 of 5
Applicant's/Registrant's Name & Address Valent BioSciences Corporation, 870 Technology Way, Liveryville, IL, 60048			Product S-Abciscic Acid (VBC-30054); TGA for Manufacturing Use Only		
Ingredient S-Abciscic Acid (S-ABA); (S)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-2-cyclohexen-1-yl)-3-methyl-(2Z,4E)-pentadienoic acid, [CAS # 21293-29-8]					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Acute Avian - 30054, WI # 529-111	47067901	Valent BioSciences EPA # 73049	OWN	
850.2200	Avian Dietary tox. Waiver S-ABA 30054: 058-f	47470521	Valent BioSciences EPA # 73049	OWN	
850.1075	Acute Fish - 30054, WI # 529A-104	47131402	Valent BioSciences EPA # 73049	OWN	
850.1010	Acute invertebrate, fresh water - 30054, WI # 529A-103	47131401	Valent BioSciences EPA # 73049	OWN	
850.4100, 850.4150	Non-target plant toxicity, S-ABA 30054:047-02	47131404	Valent BioSciences EPA # 73049	OWN	
850.4100, 850.4150	Non-target plant toxicity, S-ABA 30054:047-02REF	47153201	Valent BioSciences EPA # 73049	OWN	
850.4350	Non-target insect-honeybee, EuGAB#20071029/S1BLEU	47151201	Valent BioSciences EPA # 73049	OWN	
N/A	EarthWorm Toxicity, WI # 529-119	47470514	Valent BioSciences EPA # 73049	OWN	
850.0000	Lomon Summary of EcoTox Results, # June 2000	47470515	Valent BioSciences EPA # 73049	OWN	
850.0000	Background Review of Literature, # ABA-LS2	47470518	Valent BioSciences EPA # 73049	OWN	
850.0000	Copies of background literature papers, # ABA-LS2 REF	47470519	Valent BioSciences EPA # 73049	OWN	
860.1500	Residue Analytical method, # S-ABA 30054: 106-1	46985604	Valent BioSciences EPA # 73049	OWN	
850.1500	Fate in Grapes, residue Levels, # S-ABA 30025: 086-f	47005303	Valent BioSciences EPA # 73049	OWN	
860.1360	Multiresidue method testing Waiver, S-ABA 30054: 058-2	47470522	Valent BioSciences EPA # 73049	OWN	
Signature 			Name and Title Thomas Bade, Regulatory Manager		Date 3/8/12

Memorandum

Date: 03 / 15 / 12

To: PM 91, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

S-Abscisic Acid, Technical Grade Active Ingredient (S-ABA, VBC-30054)

FOR FORMULATION INTO PLANT GROWTH REGULATOR (PGR) PRODUCTS

FOR MANUFACTURING OR FORMULATION USE ONLY

Active Ingredient	
S-Abscisic Acid	97.9% w/w
Other Ingredients.....	2.1% w/w
Total.....	100.0% w/w

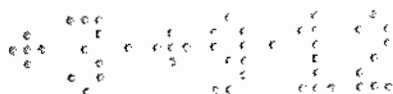
KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call toll-free 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-847-968-4700.	

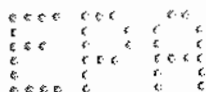
EPA Registration No. 73049-460
EPA Establishment No.

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-847-968-4700

Net Content: 25 kg, 50 kg



PRECAUTIONARY STATEMENTS



HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Mixers, loaders and handlers must wear the appropriate personal protective equipment (PPE): long sleeved shirt and pants, shoes and sock, and protective eyewear. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash-waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

S-Abscisic Acid is intended for use in the formulation of Plant Growth Regulator (PGR) products, to be applied to field and container-grown plants to induce and regulate PGR responses.

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator has complied with U.S. EPA data submission requirements regarding the support of such uses. Products made from this technical material will require registration with the U.S. Environmental Protection Agency (EPA).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container tightly closed when not in use. Store product in a cool and dry place. Avoid extended storage conditions at temperatures above 25°C (77°F).

Pesticide Disposal: To avoid wastes, use all material in this container according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry). Do not contaminate water when disposing of equipment wash-water or rinsate. Improper disposal of unused pesticide, wash-water or rinsate is a violation of federal law.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Completely empty drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Fill ¼ full with water. Shake for 10 seconds. Pour rinsate into manufacturing equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Completely empty drum contents into manufacturing equipment or a mix tank by shaking and tapping sides and bottom to loosen clinging particles. Fill container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Warranty and Disclaimer Statement:

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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